

4366. Misbranding of ovarian substance, suprarenal cortex, and spleen substance. U. S. v. 4 Bottles, etc. (F. D. C. No. 36443. Sample Nos. 39655-L to 39657-L, incl.)

LIBEL FILED: March 16, 1954, Southern District of California.

ALLEGED SHIPMENT: On or about November 13, 1952, and January 16, September 17, and November 9, 1953, by Wilson & Co., Inc., from Chicago, Ill.

PRODUCT: 4 bottles of *ovarian substance*, 16 bottles of *suprarenal cortex*, and 1 bottle of *spleen substance* at Los Angeles, Calif.

LABEL, IN PART: (Bottle) "100 5 Gr. Ct. Item No. 73 Ovarian Substance N. F. VIII * * * Dose: As administered by the physician," "100 Caps. Item No. 181 Suprarenal Cortex 2 Grains The dried and defatted product after removal of a major portion of the medulla. * * * Caution: Federal law prohibits dispensing without prescription," and "100 Caps. Item No. 164 Spleen Substance 5 Gr. Each capsule contains five grs. dried and partially defatted spleen. Caution: Federal law prohibits dispensing without prescription."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use; and, Section 503 (b) (4), the labels of the articles prior to dispensing bore the statement "Caution: Federal law prohibits dispensing without prescription," and the articles were drugs to which Section 503 (b) (1) did not apply.

DISPOSITION: April 8, 1954. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS *

4367. Misbranding of Elemin multiple vitamin and mineral tablets. U. S. v. 15 Cases * * *. (F. D. C. No. 36189. Sample No. 61927-L.)

LIBEL FILED: On or about December 15, 1953, Western District of Missouri.

ALLEGED SHIPMENT: On or about July 27, August 25, and October 21, 1953, from Berkeley, Calif.

PRODUCT: 15 cases, each containing 24 retail cartons, of *Elemin multiple vitamin and mineral tablets* at Kansas City, Mo., in possession of G & J Distributors.

LABEL, IN PART: (Carton) "Contents 360 Tablets * * * Elemin G & J Multiple Vitamins Supreme Formula * * * 240 Mineral Tablets As a Source of the Minerals Iron and Iodine Contains: Iodine and Iron as naturally present in dehydrated kelp, iron gluconate and a sedimentary mineral deposit with excipients, and artificial color added to coating. 4 Tablets per day (suggested daily intake) will provide: Iodine—not less than 0.2 Mg. 200% minimum daily adult requirement Iron—not less than 30.0 Mg. 300% minimum daily adult requirement * * * 120 Multiple Vitamin Tablets 2 Tablets daily will supply: Vitamin A 25,000 USP Units Vitamin D 1200 USP Units Vitamin B₁ 8.0 Mg. Vitamin B₂ 5.0 Mg. Vitamin B₆ 2.0 Mg. Vitamin B₁₂ 3.0 Mcg. Vitamin C 150.0 Mg. Vitamin E 10.0 Mg. Niacin 10.0 Mg. Niacinamide 40.0 Mg. Calcium Pantothenate 10.0 Mg. Inositol 10 Mg. Choline 10.0 Mg. Para Aminobenzoic Acid 10.0 Mg. Rutin 1.0 Mg. Folic Acid 1.0 Mg. Chlorophyll 1.0 Mg. Conc. Beef Liver Extract 65.0 Mg. * * * Alfalfa Concentrate, Excipients, Binders, and Artificial Color in Coating. * * * Supreme Formula is packaged in sanitary, hermetically sealed

*See also Nos. 4365, 4366.

Pocket Paks, each containing 2 Elemin Mineral Tablets and 1 G & J Multiple Vitamin Tablet."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the label of the article failed to bear directions for use in the treatment of ulcers, high blood pressure, arthritis, diabetes, polio, infantile paralysis, cancer, dormant glands, migraine headache, allergic reactions, thyroid trouble, and diarrhea, which were the conditions for which the article was intended and offered in oral statements made on November 4, 1953, by Roy M. Buck, operator of G & J Distributors, while promoting the sale of the article. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 4, 1954. Default decree of condemnation and destruction.

4368. Misbranding of Nu-Mineral capsules. U. S. v. 3 Cases * * *. (F. D. C. No. 36350. Sample No. 82454-L.)

LIBEL FILED: January 19, 1954, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about November 28, 1953, from Clarksburg, W. Va. This was a return shipment.

PRODUCT: 3 cases, each containing 216 42-capsule bottles, of *Nu-Mineral capsules* at Sharon, Pa.

LABEL, IN PART: (Bottle) "Nu-Mineral Three Capsules Supply Dicalcium Phosphate, USP 975 mgm. 30% Ferrous Sulfate, Dried, USP 135 mg. 400% Potassium Iodide, USP45 mg. 300% Manganese Sulfate, H₂O, CP 4.5 mg. Cobalt Nitrate, 6 H₂O, CP 1.5 mg. Sodium Molybdate, 2 H₂O, CP 3.0 mg. Copper Sulfate, USP 3.0 mg. Zinc Sulfate, USP 4.2 mg. Magnesium Sulfate, USP 97.5 mg. Aloin, USP 8. mg. Vitamin B-12, USP 3 mcgm. Distributed by Penn-Art Products, Sharon, Pa."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of stomach ailments, weak kidneys, rheumatic pains, arthritis, neuritis, headaches, toxins, bloating, weak back, lumbago, back pains, lack of vitality, poor appetite, atonic constipation, spastic constipation, paleness, anemia, and weak eyes, which were the conditions for which the article was offered in advertising sponsored by the distributor, Penn-Art Products.

DISPOSITION: March 12, 1954. Default decree of condemnation. The court ordered that the product be delivered to a local hospital.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4369. Adulteration and misbranding of Dexadex tablets. U. S. v. 437 Bottles * * *. (F. D. C. No. 36427. Sample No. 84339-L.)

LIBEL FILED: March 5, 1954, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 20, 1953, by Strong, Cobb & Co., Inc., from Cleveland, Ohio.

PRODUCT: 437 bottles of *Dexadex tablets* at Philadelphia, Pa. Analysis showed that the product contained 6.2 milligrams of dextro-amphetamine sulfate per tablet.

LABEL, IN PART: (Bottle) "Cabot 100 Tablets Dexadex * * * Each Tablet contains Dextro-Amphetamine Sulfate 10 mg."